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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,424	09/24/2003	Frank Berendes	CH-7929/LeA 36,206	5072
34947	7590	10/17/2005	EXAMINER	
LANXESS CORPORATION 111 RIDC PARK WEST DRIVE PITTSBURGH, PA 15275-1112			RAHMANI, NILOOFAR	
			ART UNIT	PAPER NUMBER
			1625	

DATE MAILED: 10/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/669,424

Applicant(s)

BERENDES ET AL.

Examiner

Niloofar Rahmani

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendment and response filed by applicant's date 04/21/2005 has been entered and considered carefully. Claims 17 and 18 have been cancelled. Claims 1-16 are pending. The claimed benefit of priority date is denied. There is no certified translation of the priority document. The filing date of the instant date is 09/24/2003.

2. ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 are rejected under 35 U.S.C. 101 because the claims are inoperable. The term "produce" does not define the operable scope.

Thus, the claims fail to provide reaction step(s) and the operable parameter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph. The claims lack operable steps and parameter. The claims encompassed any and all conditions for reducing the C=O moieties for which insufficient description was found in the specification.

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3. Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "derivative" is confusing. Does it mean formula II or does it means further derivation.

4. Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

To satisfy the enablement requirement a deposit must be made "prior to issue" but need not be made prior to filing the application. *In re Lundak*, 773 F.2d 1216, 1223, 227 USPQ 90, 95 (Fed. Cir. 1985).

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Claim 6 is drawn to genera *Saccharomyces*, *Geotrichum*, *Candida*, *Pichia*, *Hansenula*, *Yarrowia*, *Rhizopus*, *Mortierella*, *Mucor*, *Sporotrichum*, *Rhodotorula*, *Trichoderma*, *Aspergillus*, *Penicillium*, *Pullaria*, *Cunninghamella* and *Curvularia* with no limitation to the species. There is no record for any deposit in the prosecution record. Any species embraced by the genus including future development must be deposited in compliance with MPEP § 2404.

5. Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is drawn to all heteroaryl carbonyl compounds. No information was found in the specification that any and all heteroaryl carbonyl starting material is available without limitation to the heteroaryl moiety. Starting material is essential to the invention. Absent of starting material the public is offered mere language rather than enablement, *In re Howarth*, 210 USPQ 689.

6. Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The term "W is COOR¹" in step b is inoperable to get compound IV from the compounds II and III. The claim fails to convert from formula II and III to formula IV, which has the amide group.

7. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Dehli et al. "Enantio- and chemoselective bioreduction of β -keto nitriles by the fungus *Curvularia lunata*", Tetrahedron, vol. 11, pages 3693-3700. Dehli et al. disclosed the process of making the instant claimed product where in R is 2-furan in the presence of microorganisms, organic solvent such as the fungus *C. lunata* CECT 2130, see pages 3695 and 3696. On the page 3695 reaction scheme, each and every element of the instant claim is disclosed. Therefore anticipation was found.

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8. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 103(a) as being unpatentable over Dehli et al." Enantio- and chemoselective bioreduction of β -keto nitriles by the fungus *Curvularia lunata*", Tetrahedron, vol.11, pages 3693-3700 in view of in view of Wermuth G Camille, "The Practice of Medicinal Chemistry", pages 205-214.

Determination of the scope and content of the prior art (MPEP §2141.01)

Dehli et al." Enantio- and chemoselective bioreduction of β -keto nitriles by the fungus *Curvularia lunata*", Tetrahedron, vol.11, pages 3693-3700 disclosed anticipatory process of the claims (see supra).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

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The difference between the instant claims and the prior art process is that the instantly claimed process employs R being heteroaryl instead of the broader R groups of the prior art being 2-Fur or Ph. Wermuth taught that heteroaryl rings have isosteric similarity (p. 213) and heteroaryl and aryl rings are considered isosteres equivalence (p.206).

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the process of Dehli et al. employing analogous heteroaryl compounds such as the isosteres of aryl and heteroaryl (Wermuth) in the process because it has been demonstrated by the reference to be operable for both heteroaryl and aryl moiety thus their isosteres.

9. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S.1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

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2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-9 are rejected under 103(a) as being unpatentable over CABON^{ab} et al. "The Microbial Reduction of 2-chloro-3-oxoesters", Tetrahedron, vol.6, pages 2199-2210 in view of Dehli et al." Enantio-and chemoselective bioreduction of β -keto nitriles by the fungus *Curvularia lunata*", Tetrahedron, vol.11, pages 3693-3700.

Determination of the scope and content of the prior art (MPEP §2141.01)

CABON^{ab} et al. "The Microbial Reduction of 2-chloro-3-oxoesters", Tetrahedron, vol.6, pages 2199-2210 disclosed analogous process of making the claimed product where in compound of formula 1 converting to the corresponding of formula 2 where in R is aryl.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process is that the instantly claimed process employs R being heteroaryl instead of the prior art R group art being aryl. The Dehli et al." Enantio-and chemoselective bioreduction of β -keto nitriles by the fungus *Curvularia lunata*", Tetrahedron, vol.11, pages 3693-3700 teaches R being heteroaryl and aryl, are analogous operable.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the process of CABON^{ab} et al. "The Microbial Reduction of 2-chloro-3-

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oxoesters", Tetrahedron, vol.6, pages 2199-2210, with addition heteroaryl starting material because Deli et al. has demonstrated heteroaryl material would be expected to operate analogously to give the desired final product.

10. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S.1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10-16 are rejected under 103(a) as being unpatentable over Houson et al. WO 2004/024708 in view of Wermuth G Camille, "The Practice of Medicinal Chemistry", pages 205-214.

Even if Certified English Translation will be presented, the effective priority benefit of WO 2004/024708 is 09/16/2002 prior to the benefit of the instant application.

Determination of the scope and content of the prior art (MPEP §2141.01)

Houson et al. WO 2004/024708 disclosed analogous process of making the claimed product wherein compound of formula (3) is converted to the corresponding compound of formula (1) through microbial catalytic process (see p.21-23).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the prior art process is that the instantly claimed process employs heteroaryl broadly instead of the more limited 5 member single heteroatom aromatic material of the prior art.

Finding of prima facie obviousness-rational and motivation (MPEP §2142.2143)

One having ordinary skill in the art would be motivated to modify the process of Houson et al. employing analogous heteroaryl compounds such as the isosteres of aryl and heteroaryl (Wermuth) in the process because isosteric heteroaryl material is expected to have analogous operability (Wermuth).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no

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longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Niloofar Rahmani

09/26/2005

N.R.


Cecilia Tsang

Supervisory Patent Examiner

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